Updating Profile Data in FACTS

(This information is provided by DCIQA, formerly MPQAS)

Profile data must be updated in FACTS to establish or update a firm's profile information (see profiling criteria below). This should be by the investigator in the preparation of the inspection record in FACTS before setting "awaiting endorsement." Or in the case of a potential OAI inspection, as soon as the investigator and supervisor concur there is a reasonable probability the inspection may result in an OAI recommendation. (Note: an ad hoc compliance work can be created at the same time a profile is set to "FI.") For foreign inspections, a CI/Potential OAI situation should be entered into FACTS during the foreign inspection trip. If this is not possible, FAX the Potential OAI Notification to HFC-240 at (301)827-0343 while the inspection is in progress.

The FACTS investigator role:

For Domestic Inspections:
Record in "initial" an "AC" for inspections classified as NAI or VAI.
Record in "initial" an "FI" immediately upon determining the inspection may be classified as OAI. HFC-240 requires a hard copy or e-mail documentation of all Potential OAI Notifications as soon as the “FI” is entered into FACTS.

For Foreign Inspections:
Notification should be FAXed or e-mailed as soon as the potential OAI situation is known, regardless of whether or not the FACTS profile data has been updated.
Whether the initial is “AC” or “FI” record “Will Refer to Compliance (with date)” in the “Initial” remarks section.

NOTE: For all Device inspections (foreign or domestic) record all applicable profiles for the establishment as having been covered if the inspection was at a minimum a Level 1, Abbreviated Inspection.

For all Drug inspections done utilizing the top-down, systems approach, the same will apply.

The FACTS IB supervisor role:

For Domestic Inspections:
In the case of a NAI or VAI inspection set the "Record Final" status to "AC" when endorsing the inspection in FACTS.
In the case of a potential OAI inspection the supervisor adds, "referred to Compliance (with date)” in the “Initial” remarks section.

For Foreign Inspections:
The supervisor verifies the investigator has properly completed his/her role. (Compliance, in the appropriate Center, will set the “Record in Review” status when they receive the EIR and “Record Final” when they finish their review.)

DO NOT record “Final” for any profile class at the District level for any foreign inspection record.

For Biologics Core Team OAI Inspections (Foreign and Domestic):
The Team’s compliance officers in OE will set the “Record in Review” status when they receive the EIR and “Record Final” status when they finish their review and consultations with CBER.

The FACTS District compliance role:
For potential OAI inspections, set FACTS to Record in Review as soon as the inspection is submitted to compliance branch for evaluation.
Use the Remarks box to keep track of the progress of the review. Include in “remarks” if the action is submitted to a Center or Counsel (date) for further review or opinion.
After the final evaluation, close the inspection in Final with the District’s decision. Include type of action taken and date of action.

Profile Process

1. Prior to the inspection, the investigator should review the firm's profile information and, if possible during the inspection, evaluate the firm's capability to produce products in the listed profile class(es). Cover as many profile classes as possible.
2. Update information for all the profile classes covered during the inspection. (When performing a top-down, systems-type inspection for medical devices and drugs (pilot GMP program) all profile classes applicable to the establishment and its products can be considered to have been covered by the inspection.)
3. Add any new profile classes.
4. Include the last date of the inspection and the compliance status. Use the remarks column to clarify information, to note product specific problems, and/or to note any regulatory action recommended or taken and the date of such action.
5. When a firm no longer manufactures products in a listed profile class, "Discontinue" those class(es) in the profiles screen of FACTS. Contact DCIQA (HFC-240) if the wrong profile class code was used, e.g., PRF instead of OPT for contact lenses/glasses. In order to remove the wrong PC from the history in FACTS, it must be deleted (not to be confused with a discontinued PC).
6. When profile classes BMI, NEC SOL, or MIS are used to identify product(s) not elsewhere classified, be sure to use the remarks section to identify the product(s).
7. Make name and/or address changes using FACTS Firm Maintenance.
8. When a firm is doing business under a different name, use FACTS Firm Maintenance to list DBAs.
9. If a firm is found to be unacceptable by a district (or in the case of foreign inspections, by the Center), any regulatory action recommended and the date must be noted in the remarks section of "In Review" in FACTS. The same is true for “Record Final.” The remarks section must include any regulatory action taken and the date. This block is updated accordingly as the work travels through the compliance subsystem of FACTS.
10. If the deficiencies are product(s) specific within a profile class, and the overall profile class status is considered acceptable, the initial profile status should be made “AC” and the initial remarks status should be made “FI” for the product specific item. Note in the remarks section the reason for the product specific status (include the product(s) when possible) and referred to compliance for review. Compliance should then either concur with the initial product specific “FI,” reach a conclusion as to the warranted regulatory action to be taken, or make the product acceptable and enter as “AC” as the final profile status. If compliance concurs with the initial “FI” and concludes the product specific item is unacceptable, the final remarks status should be made “UN” and the remarks section updated with the regulatory action and the date action taken. Remarks section should state the other products in the profile class are acceptable.
11. When a profiled firm goes out of business, changes operations, or discontinues production of FDA regulated products, record the appropriate information in the FACTS OEI and remember to remove the profile required flag.
12. Update Operation type from drop down menu:
    a. For devices: If a firm makes sterile products , include the appropriate profile class(es) for the product(s) manufactured and, whether the sterilization is performed on-site or by a contract sterilizer, include the appropriate sterilization profile class code. Use the Remarks box to indicate “on-site sterilization” or “off-site sterilization” as appropriate. For off-site sterilization include the name of the sterilizer, city and state/country in Remarks.
    b. If a firm is a contract sterilizer only, use the appropriate sterilization profile class code, and note in the remarks column "contract sterilizer only."
    c. If a firm is a control-testing laboratory for its own products do not use CTL. If the firm does validation, stability, etc., work for other firms, use the CTL profile class code and from the “Operation Type” drop down menu choose “Control Testing Lab Also” and indicate in the remarks section “Drug,” “Device,” or “Biologic.
    d. If a firm is a control testing laboratory only, use the CTL profile class code and from “Operation Type” drop down menu choose “Control Testing Lab Only” and indicate in the remarks section “Drug,” “Device,” “Biologics” (or a profile status combination of the three, e.g., “Drugs and Devices”) as appropriate.
13. The use of “Others” as found on the Profile Status (Final) pull down menu.
    a. When a firm is operating under a **Consent Decree** the Final profile status should be “Others” rather than acceptable or unacceptable. The Remarks Status field should reflect the status of the current inspection (acceptable or unacceptable) and the Remarks field should elaborate on the current inspection and state that the firm is operating under consent decree (date). The consent decree information should be carried forward to each new inspection until the consent decree is lifted. If and when it is lifted use the remarks section to record consent decree lifted and the date it was lifted.
    b. When a firm is operating under an **Application Integrity Policy** (AIP) the final profile status should be “Others” rather than acceptable or unacceptable. The Remarks Status field should reflect the current inspection (acceptable or unacceptable) and the Remarks field should state that the firm is under AIP on a product by product basis. If feasible list the product(s) under AIP. This should be carried forward to each new inspection under the AIP until it is removed. Use the “Remarks" section to record removal of the AIP and the date.

14. The Inspection Date never changes. For profiling purposes it is the last date of the inspection entered in the EI record. The Status Date is the date the status was initially entered. The Status date provides an audit trail and should not be backdated or changed.
15. There are times the district's course of action for an OAI inspection is not to immediately issue a Warning Letter or take regulatory action, but instead seek compliance via an alternative means. For these cases, the profile status for the OAI inspection should not be finalized. Instead, the compliance officer should enter the "record in review" as "pending" and track the action in the "remarks" field. **If a reinspection is required, the investigator must "uncheck" the profile required box on the "Maintain Inspection Results Screen" before entering the information of the inspection.** Unchecking the profile required box avoids the "normal requirement" to update the profile for the inspection. If this inspection is found to continue to be OAI, the investigator should note in the Remarks field and indicate the reinspection is referred to compliance. The compliance officer has the responsibility to update the Remarks in "record for review" and track any corresponding action on the Profile screen via the Original Inspections Result Screen. When a compliance action is taken, e.g., Warning Letter issued, Compliance should access the original Maintain Profile Screen through the original Inspections Result Screen and enter the firm's "Final" profile status. This pr3events two screens open concurrently and dissuades entering a final status of "unacceptable" when alternative corrective action is taken. The "record in review" "pending" status can remain open for as long as required and can be edited repeatedly, until a final decision is made.

NOTE: The GMP "Last Final Status" field [top portion of profile screen-Profile Classes] should always be OT for firms under a Consent Decree or Application Integrity Policy. Setting the Profile Status (in Final) to "Others" will accomplish this.

16. When to use profile status codes HO (hold) and PN (pending):
    a. PN – Compliance work is being done on the item. Use for all work sent to Compliance. Remarks should be updated to reflect overall status, action and action status.
    b. HO – Used for any compliance work referred to ORA/HQ, OCC or Centers for review. Could be used for a number of reasons that cause any compliance component to stop work on the item, e.g., awaiting policy decisions, temporary abeyance, etc.

Establishment Profile Criteria

Profile the following device, biologic, human and veterinary drug establishments:

Manufacturer	Makes a new or a changed product from one or more ingredients.
Remanufacturer	A person who processes, conditions, renovates, repackages, restores, or performs any other act to a finished device that significantly changes the device's performance or safety specifications or intended use.
Reprocessor	A person who performs remanufacturing operations on a single-use device.
Packer/ Repacker	The establishment packs a product or products into different containers without making any changes in the form of the product.
Labeler/ Relabeler	An establishment which affixes the original labeling to a product or changes in any way the labeling on a product without affecting the product or its container.
Contract Sterilizers	Performs sterilization or irradiation of products or components of products regulated by FDA on a contract basis.
Control Testing Laboratories	Performs production quality control work related to products regulated by FDA on a contract basis.
Assemblers of Medical Device Kits	Person or establishment responsible for assembling finished devices into medical device kits.
Tissue Establishments	Manufacturers of tissues, cellular or tissue-based products regulated as devices subject to QS/GMPs, and those regulated as biological products (under section 351 of the PHS Act) subject to drug GMPs should be profiled. See CBER website: http://www.fda.gov/cber/tissue/tislist2.htm
Specification Developer	A person who initiates or develops specifications for a device that is distributed under the establishment's own name but is manufactured by a second person.

The following establishment and operation types are not profiled.

Blood Banks
Methadone Clinics
Manufacturers of “Research Use Only” Products
Pharmacies and Retail firms
Distributors
Plasmapheresis Centers
Custom Device Manufacturers
Veterinary Medical Device Firms
X-ray Assemblers
Mammography Clinics
Manufacturers of General Purpose Articles (Devices)
Physicians Offices, Hospitals and Clinics
Laser Light Shows/Television and Microwave Oven Manufacturers
Suntanning Establishments
Device Component Manufacturers
Clinical Investigators/Bioresearch Monitoring
Tissue firms inspected under 21 CFR 1270, (see CBER website: http://www.fda.gov/cber/tissue/tislist2.htm)
Any Non-GMP Inspection

For more information contact your District Profile Coordinator, DCIQA [(301)827-0390] or the DCIQA web page on the ORA Intranet.

Profile Class Codes with Definitions:

BIOLOGICS

AEV	ANTITOXINS, ANTIVENINS, ENZYMES, AND VENOMS
AFP	ANIMAL DERIVED FRACTIONATION PRODUCTS
ALP	ALLERGENIC PRODUCTS
BGR	BLOOD GROUPING REAGENTS
BMI	BIOLOGICAL PRODUCTS NOT OTHERWISE CLASSIFIED (LAL, BLOOD COLLECTION BAGS WITH ANTI-COAGULANT, ETC., WHEN USING THIS PROFILE CLASS NOTE SPECIFIC PRODUCT(S))
BTP	BIOLOGICAL THERAPEUTIC PRODUCTS
CBS	COMPUTER BIOLOGICAL SOFTWARE
HFP	HUMAN DERIVED FRACTIONATION PRODUCTS
SMC	SOMATIC CELLULAR PRODUCTS
TIS	HUMAN TISSUE REGULATED BY FDA
TOX	TOXOIDS/TOXINS
TRP	THERAPEUTIC RECOMBINANT PRODUCTS
VBP	VACCINE BULK PRODUCT
VFP	VACCINE FINISHED PRODUCT
VIV	IN VIVO DIAGNOSTICS
VTK	VIRAL MARKER TEST KIT

DRUGS

ADM	AEROSOL DISPENSED MEDICATION
CBI	BIOTECHNOLOGY CRUDE DRUGS
CEX	PLANT/ANIMAL EXTRACTION CRUDE DRUG
CFN	NON-STERILE BULK BY FERMENTATION CRUDE DRUGS
CFS	STERILE BULK BY FERMENTATION CRUDE DRUGS
CHG	CAPSULES, PROMPT RELEASE
CRU	CRUDE BULK DRUGS (NON-SYNTHESIZED)
CSG	CAPSULES, SOFT GELATIN
CSN	NON-STERILE BULK BY CHEMICAL SYNTHESIS
CSS	STERILE BULK BY CHEMICAL SYNTHESIS
CTL	CONTROL TESTING LABORATORIES (WHEN USING THIS PROFILE CLASS NOTE IN REMARKS "DRUGS")
CTR	CAPSULES, MODIFIED RELEASE
GAS	MEDICAL GAS (INCLUDES LIQUID OXYGEN)
LIQ	LIQUIDS (INCLUDES SOLUTIONS, SUSPENSIONS, ELIXIRS, TINCTURES, ETC.)
LVP	LARGE VOLUME PARENTERALS
NEC	NOT ELSEWHERE CLASSIFIED (WHEN USING THIS CLASS, NOTE THE SPECIFIC PRODUCT(S))
OIN	OINTMENTS, NON-STERILE (INCLUDES CREAMS, JELLY, PASTE, ETC.)
POW	POWDERS (INCLUDES ORAL AND TOPICAL)
SNI	STERILE NON-INJECTABLE
SUP	SUPPOSITORIES
SVL	SMALL VOLUME PARENTERALS (LYOPHILIZED)
SVS	STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS

SVT	TERMINALLY STERILIZED SMALL VOLUME PARENTERALS
TCM	TABLETS, PROMPT RELEASE
TCT	TABLETS, DELAYED RELEASE
TDP	TRANSDERMAL PATCHES
TTR	TABLETS, EXTENDED RELEASE

NOTE: CCS and SVP are no longer used.

DEVICES

BBP	BLOOD AND BLOOD PRODUCTS FOR FURTHER MANUFACTURING(reinstated 1/01)
CCR	CLINICAL CHEMISTRY REAGENTS (INCLUDES DIAGNOSTIC TAPES, STICKS, ETC.)
COH	COMPUTER HARDWARE
COS	COMPUTER SOFTWARE (OTHER THAN BIOLOGICS)
CSP	CHEMICAL STERILIZATION
CTL	CONTROL TESTING LABORATORIES (WHEN USING THIS PROFILE CLASS, NOTE IN REMARKS "DEVICE")
DKA	DEVICE KIT ASSEMBLER
ELE	ELECTRICAL ASSEMBLY
FSP	FILTRATION STERILIZATION
GLA	GLASS OR CERAMIC FABRICATION AND ASSEMBLY
GSP	GAS STERILIZATION (ETO, PROPYLENE OXIDE)
HCP	HEMOTOLOGY AND COAGULATION PRODUCTS (reinstated 1/01
HSP	DRY HEAT STERILIZATION
MED	MEDIA (INCLUDES MICROBIOLOGICAL AND TISSUE CULTURE, GROWTH MEDIA AND ACCESSORIES, INCLUDING INGREDIENTS)
MIS	NOT ELSEWHERE CLASSIFIED (NOTE SPECIFIC PRODUCT(S) IN REMARKS)
MTL	METAL FABRICATION AND ASSEMBLY
OPT	OPTIC FABRICATION AND ASSEMBLY (CONTACT AND OTHER LENSES, EYEGLASS, ETC.)
PBM	PROCESSED BIOLOGIC MATERIAL (reinstated 1/01)
PRF	PLASTIC OR RUBBER FABRICATION AND ASSEMBLY
RIP	RADIOIMMUNOASSAY PRODUCTS
RSP	RADIATION STERILIZATION
SIP	SEROLOGICAL AND IMMUNOLOGICAL PRODUCTS (INCLUDES BACTERIAL TYPING, RHEUMATOID FACTORS, PREGNANCY KITS, IVD other than VIRAL MARKER TEST KITS, ETC.)
SOL	DEVICE SOLUTIONS AND GELS (INCLUDES CONTACT GELS, DIALYSIS SOLUTIONS, DENTAL PASTES, ADHESIVES, ETC.)
SSP	STEAM STERILIZATION
SPD	SPECIFICATION DEVELOPERS
TSP	FRACTIONAL TYDALLIZATION STERILIZATION
TXT	TEXTILE FABRICATION AND ASSEMBLY
WOD	WOOD FABRICATION AND ASSEMBLY
WSP	WATER STERILIZATION